

10/551933
JC20 Rec'd PCT/PTO 04 OCT 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Ali, et al.

Serial No. To be assigned

Filed:

For: SELECTIVE SPIROCYCLIC GLUCOCORTICOID
 RECEPTOR MODULATORS

Art Unit: _____

Examiner: _____

Commissioner for Patents
 P.O. Box 1450
 Alexandria, Virginia 22313-1450

**INFORMATION DISCLOSURE STATEMENT
 UNDER 37 CFR 1.97**

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By _____ Date _____

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5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application *and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.*
- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,



By: Raynard Yuro

Attorney _____ For Applicant(s)

Reg. No. 45,570

MERCK & CO., INC.

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(732)594-0182

Date: October 4, 2005

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				COMPLETE IF KNOWN	
				Application Number	To be assigned 10/551933
				Filing Date	
				First Named Inventor	Ali, et al.
				Group Art Unit	
				Examiner Name	
				Attorney Docket Number	21150P
Sheet	1	of	2		

[illegible][illegible]

Examiner Signature		Date Considered	
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*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				COMPLETE IF KNOWN	
				Application Number	To be assigned 10/551933
				Filing Date	04 OCT 2005
				First Name(s) of Inventor	Ali, et al.
				Group Art Unit	
				Examiner Name	
Sheet	2	of	2	Attorney Docket Number	21150P

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Hirschmann, et al., "Synthesis and Structure of Steroidal 4-Pregнено[3,2-c]Pyrazoles. A Novel Class of Potent Anti-Inflammatory Steroids", J. Am. Chem. Soc., Vol. 85, pp. 120-122 (1963)
		Hirschmann et al., "Methylated Steroids. IV. 6,16a-Dimethyl-Hydrocortisone and Related Compounds", J. Am. Chem. Soc., Vol. 85, pp. 236-238, (1963)
		Hirschmann, et al., "Synthesis and Structure of Steroidal Pregn-4-eno-and 5a-Pregnano[3,2-c]pyrazoles. A Novel Class of Potent Anti-Inflammatory Steroids", J. Am. Chem. Soc., Vol. 86, pp. 1520-1527 (1964)
		Hirschmann, et al., "Synthesis of Pregn-4-eno[3,2-c]pyrazoles Related to 9a-Fluoro-16a-methylcortisol", J. Med. Chem., Vol. 7, pp. 352-355, (1964)
		Robert Newton, "Molecular mechanisms of glucocorticoid action: what is important?", Thorax, Vol. 55, pp. 603-613, (2000)
		Schane, et al., "Glucocorticoid/Antiinflammatory activities of Nonsteroidal Phenylpyrazoles in the Rat", Steroids, Vol. 45, No. 2, pp. 171-185, (1985)

Examiner Signature		Date Considered	
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